UNITED STATES DISTRICT COURT DISTRICT OF CONNECTICUT

Applera Corporation and : Roche Molecular Systems, Inc.,: plaintiffs, :

:

v. : 3:98cv1201 (JBA)

:

MJ Research Inc. and Michael and John Finney

Claim Construction of Disputed Terms in U.S. Patents 5,333,675, 5,656,493, and 5,475,610

On June 11, 12, and 18, 2003, a Markman hearing was held to aid the Court in construing disputed terms in claims 17, 33, and 45 of U.S. Patent 5,333,675 (the "'675 Patent"), claim 16 of U.S. Patent 5,656,493 (the "'493 Patent"), and claims 1, 44, 158, 160, 161 and 163 of U.S. Patent 5,475,610 (the "'610 Patent"), which plaintiffs claim defendants have infringed or induced infringement of. See Markman Tr. Vol. I [Doc. #681], Vol. II [Doc. #682]. The Court's construction of the disputed terms is set forth below.

I. The '675 Patent

A. Claim 17

Claim 17 of the '675 Patent depends from claim 11.

Accordingly, the Court construes claim 17 as containing all the limitations of claim 11. Claim 11, with underlined text showing the language of claim 17, reads as follows:

Apparatus capable of cycling a reaction mixture in a polymerase chain reaction mixture in a polymerase chain reaction process that includes multiple cycles of the steps of thermal denaturation of double stranded DNA, primer annealing to single-stranded DNA and primer extension by a DNA polymerase, said apparatus comprising:

- a heat-conducting container for holding a reaction mixture;
- means for heating and cooling said container to or at any of a plurality of temperatures and having a control input for receiving a control signal controlling whether said container is heated or cooled, which heating and cooling means includes a Peltier device;
- a computer means, coupled to said control input of said means for heating and cooling, comprising means for receiving, storing, and accessing a plurality of checkpoints from a user, each said checkpoint comprising a first time, said first time being a function of the time for which said container is to be maintained at one temperature of said plurality of temperatures, said accessing a plurality of checkpoints comprising generating control signals therefrom at the control input of said means for heating and cooling to cause said temperature to be achieved at said container and maintained for said time for which said container is to be maintained at said one temperature;
- wherein said computer means further comprises usercontrollable means for arranging said checkpoints in a
 sequence in which they are to be automatically accessed
 upon a command from the user, and user-controllable
 means programmed to produce at least one subset of
 sequenced checkpoints defining temperatures and times
 for a selected cycle of thermal denaturation of doublestranded DNA, primer-annealing to single-stranded DNA
 and primer extension by a DNA polymerase, where said
 subset is less than the total number of checkpoints
 which will be accessed in sequence, which can be
 repeated a user-defined number of times before the
 checkpoint following the last checkpoint in the subset
 of sequence checkpoints is accessed.

1. Preamble

The preamble is not limiting because it describes a use of an invention and because the body of the claim defines a structurally complete invention capable of PCR such that deletion of the preamble would not affect that structure. See Catalina Marketing Intern'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808-09 (Fed. Cir. 2002). Even if the preamble were construed as a limitation of the claim, the language "capable of" does not require that the apparatus must actually be used to perform PCR.

2. "means for heating and cooling said container to or at any of a plurality of temperatures"

The parties agree that this limitation is subject to 35 U.S.C. § 112, which provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

"The first step in construing such a limitation is to identify the function of the means-plus-function limitation," <u>Texas</u>

<u>Digital Systems</u>, <u>Inc. v. Telegenix</u>, <u>Inc.</u>, 308 F.3d 1193, 1208

(Fed. Cir. 2002), mindful that "[w]hen construing the functional statement in a means-plus-function limitation, we must take great care not to impermissibly limit the function by adopting a function different from that explicitly recited in the claim,"

Generation II Orthotics Inc. v. Medical Tech., Inc., 263 F.3d 1356, 1364-65 (Fed. Cir. 2001). Here, the function is "heating and cooling said container to or at any of a plurality of temperatures." The language, "having a control input for receiving a control signal controlling whether said container is heated or cooled," does not recite additional function but identifies additional structure by which the means performs its function.

"The next step is to identify the corresponding structure in the written description necessary to perform that function,"

Texas Digital, 308 F.3d at 1208, understanding that "'[s]tructure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.'"

Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1375 (Fed. Cir. 2003) (quoting B. Braun Med. v. Abbott Labs., 124 F.3d 1419, 1424 (Fed. Cir. 1997)). "Section 112 paragraph 6 does not 'permit incorporation of structure from the written description beyond that necessary to perform the claimed function.'" Asyst Tech.,

Inc. v. Empak, Inc., 268 F.3d 1364, 1369-70 (Fed. Cir.

The Court's interpretation of the clause as connoting additional structure comports with the meaning of "control input" as defined by those with skill in the relevant art. See McGraw-Hill Dictionary of Scientific and Technical Terms (Sybil P. Parker ed., 3rd ed. 1984) ("the terminals to which the power or signal is applied"); Webster's New World Dictionary of the Amer. Language (David B. Guralnik ed., 2d college ed. 1984) ("a terminal connection for receiving electric power or signals"). The specification does not demonstrate that the patentee acted as an independent lexicographer with respect to this term.

2001) (quoting Micro. Chem., Inc. v. Great Plains Chem. Co., 194

F.3d 1250, 1257-58 (Fed. Cir. 1999)). "Structural features that
do not actually perform the recited function do not constitute
corresponding structure and thus do not serve as claim
limitations." Id. at 1370. "The duty to link or associate
structure in the specification to the recited function is the
quid pro quo for the convenience of employing § 112, paragraph
6." Texas Digital, 308 F.3d at 1208-09.

In the specification, the structure linked to the recited function of "heating and cooling said container to or at any of a plurality of temperatures" is any heating and cooling apparatus which can perform the recited function provided such apparatus includes the heat exchanger, is capable of reaching and sustaining the required temperatures, and achieves the user-defined temperature versus time profile. See '675 Patent, col. 8, 11. 18-32; see also '675 Patent, col. 6, 11. 25-30. In addition, claim 17 further requires that the structure for heating and cooling includes a Peltier device. The structure may but does not have to include the heat pump, heat sink, and hot and cold fluid reservoirs illustrated in Figures 1 and 2. See '675 Patent, col. 8, 11. 12-47; col. 8, 1. 65 - col. 9, 1. 5.2

² The specification does not identify any embodiment combining a heat pump with a fluid reservoir or water bath for the purpose of "heating or cooling said container." Rather, '675 Patent, col. 22, 11. 3-34 provides that the hot and cold fluid reservoirs and the fluid control multiplexer illustrated in Figure 13 "could be dispensed with" in favor of a heat pump driver and attendant heat pump.

In the preferred embodiment, the heat exchanger is a metal heat-conducting block, <u>see</u> '675 Patent, col. 8, ll. 3-5, and, as the parties' respective claim constructions agree to limit the claim to this form, the Court will adopt it as well. The heat exchanger (here a heat-conducting metal block) requires a reaction well (or vessel), <u>see</u> '675 Patent, col. 7, l. 63-66, which may be a recess machined into the heat exchanger or may be a plastic container which holds fluids and sits in a recess formed in the heat exchanger, <u>see</u> '675 Patent, col. 7, l. 66 - col. 8, l. 3; col. 8, ll. 18-23; col. 9, ll. 32-35. Even if a particular embodiment utilizes a "reaction well (40) which [is] a recess machined into the heat exchanger [(10)]," '675 Patent, col. 7, l. 66-67, there is nothing in the specification requiring that recess to be in the top surface of the heat exchanger.³

The memory, cpu, heat pump interface, and connectors are not corresponding structure that performs the recited function.

Whereas the heat pump and other apparatus are said to perform the function of heating and cooling the reaction well and the fluids therein, and the heat exchanger is said to perform the function of exchanging the heat or cold from the heating and cooling apparatus to the reaction well, see e.g., '675 Patent, col. 8, ll. 18-32, the software, circuitry, and heat pump interface are variously described as enabling ("causing" or "controlling") the

Figures 1 and 2 show a "reaction well" (or "vessel") (40) adjacent to the heat exchanger (10) but do not illustrate the location of any recess.

heating or cooling, <u>see e.g.</u>, '675 Patent, col. 10, 11. 11-17, 29-45; col. 12, 11. 47-53; col. 16, 11. 15-18, not actually performing the heating or cooling function. <u>See Asyst</u>, 268 F.3d at 1371 ("The corresponding structure to a function set forth in a means-plus-function limitation must actually perform the recited function, not merely enable the pertinent structure to operate as intended..."). Viewed in its entirety, claim 17 itself suggests this differentiation between capability and control, distinguishing between "means for heating and cooling said container to or at any of a plurality of temperatures" and the receipt of a control signal from the "computer means" in turn "controlling whether said container is heated or cooled," '675 Patent, col. 62, 11. 12-13, which subsumes when, how much, and for how long the container is heated or cooled, <u>see</u> '675 Patent, col. 62, 11. 22-27.

3. "a computer means ... said accessing a plurality of checkpoints comprising generating control signals therefrom at the control input"

The parties agree that this limitation is subject to 35 U.S.C. § 112. Here, the function is "receiving, storing and

⁴ The sole reference in the specification to "control apparatus" as "heat pump interface plus heat pump" which in turn heats the heat exchanger, see '675 Patent, col. 13, ll. 17-21, is too imprecise to outweigh the otherwise carefully-maintained distinction between causing and controlling the heating and cooling done by the heat pump interface, circuitry, and software, and the heating and cooling of the reaction well performed by the heat pump (and other apparatus) and heat exchanger.

accessing a plurality of checkpoints from a user, ..., said accessing a plurality of checkpoints comprising generating control signals therefrom at the control input of the means for heating and cooling to cause said temperature to be achieved ... and maintained...."

The structure linked to the recited function in the specification is a computer, <u>see</u> '675 Patent, col. 10, ll. 11-33; col. 20, l. 57 - col. 21, l. 4, which is programmed to run with a process control algorithm, <u>see e.g.</u>, '675 Patent, col. 8, ll. 56-61; col. 18, ll. 20-24; col. 21, ll. 5-7.

The corresponding structure is not limited to the pulse width modulation control algorithm of a preferred embodiment disclosed at '675 Patent, col. 12, 11. 54-60. The claim language does not specify pulse width modulation control signals but uses the more general phrase "control signals." The specification's "standard process control algorithms," '675 Patent col. 8, 11. 56-61; col. 18, 11. 20-24, is linked with the function of "generating control signals ... to cause ... said temperature to be achieved ... and maintained," id.; see Medical Instruments and Diagnostics Corp. v. Elekta AB, 344 F.3d 1205, 1217-1219 (2003); would be understood by one skilled in the art to encompass a computer program for performing that function, see id. at 1211-12; and adequately discloses sufficient structure for one skilled in the art to create such a program, see In re Dossel, 115 F.3d

942, 946 (Fed. Cir. 1997); see also Applera Markman App. [Doc. #678] Ex. 20 (Deposition of Richard Leath) at 262:9-22.

4. "user-controllable means programmed to produce at least one subset of sequenced checkpoints defining temperatures and times for a selected cycle of thermal denaturation of double-stranded DNA, primer annealing to single-stranded DNA and primer extension by a DNA polymerase, where said subset is less than the total number of checkpoints which will be accessed in sequence, which can be repeated a user-defined number of times before the checkpoint following the last checkpoint in the subset of sequence checkpoints is accessed."

The parties agree that this limitation is subject to 35 U.S.C. § 112. The function here is "produc[ing] at least one subset of sequenced checkpoints defining temperatures and times for a selected cycle of [PCR]." The "subset" is further defined as "less than the total number of checkpoints which will be accessed in sequence, which can be repeated a user-defined number of times before the checkpoint following the last checkpoint in the subset of sequenced checkpoints is accessed."

The function does not include linking to a separate program after cycling a subset of sequenced checkpoints, that is, linking to multiple temperature profiles. First, claim 17 does not identify an explicit linking function. See Generation II

Orthotics, 263 F.3d at 1364-65. Second, application of the doctrine of claim differentiation, see e.g., Wenger Mfg. Inc. v.

Coating Mach. Sys., Inc., 239 F.3d 1225, 1233-34 (Fed. Cir.

2001); Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1303-05 (Fed. Cir. 1999), weighs against construing the function to include linking as the patentee knew how to claim a linking function when desired.⁵

The qualifying subordinate clauses that further define "subset" - "where said subset is less than the total number of checkpoints which will be accessed in sequence" and "which can be repeated a user-defined number of times before the checkpoint following the last checkpoint in the subset of sequenced checkpoints is accessed" - do not recite a linking or any other additional function. They describe what occurs after the subset of checkpoints, a PCR cycle, has run (whether or not such cycle is repeated a user defined number of times): namely, the first checkpoint of a new temperature profile is accessed. While the claim requires the user controllable means to produce at least one subset of sequenced checkpoints, it is not further required to access another checkpoint following that subset. See also Applera Markman App. [Doc. #678] Ex. 21 (Deposition of Richard Leath) at 409:9-410:6.

There is nothing in the prosecution history that rises to

⁵ <u>See</u> '675 Patent, col. 63, ll. 52-56 (Claim 22: "... wherein said computer means includes means to define a plurality of temperature profiles; and further comprising user-controllable means to link a plurality of said temperature profiles in a sequence to form a protocol"); col. 68, ll. 36, 41-43 (Claim 49: "a plurality of temperature profiles to be applied in a sequence ... a link data item identifying the next temperature profile in the sequence of profiles"); <u>see also</u> '675 Patent, col. 65, ll. 4-11 (Claim 28); col. 66, ll. 7-11 (Claim 31).

the level of a prosecution disclaimer so as to override the heavy presumption that Claim 17 carries its ordinary meaning, here, one not including a linking function. See Omega Eng'g Inc. v. Raytek Corp., 334 F.3d 1314, 1323-26 (Fed. Cir. 2003); see also Texas Digital, 308 F.3d at 1204 ("Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.").6

The references cited by defendants apply to the history of claims that contained explicit linking functions and are not asserted in this litigation. See Applera Markman App. [Doc. #678] Ex. 22 at 1-2, 9-12; Defs. Markman App. Vol. 1 [Doc. #642] Ex. 16 at 1-2, Ex. 19 at 4-5, 26-27, 32-33, Ex. 20 at 1-5, Ex. 21 at 6; see also infra note 9.7

⁶ A recent albeit unpublished analysis rejects defendants' assertion that the prosecution history estoppel doctrine elaborated on in Warner Jenkinson Co. v. Hilton Davis Chem Co., 520 U.S. 17 (1997), and Festo Corp. v. Shoketsu Kinzoku Koqyo Kabushiki Co., 535 U.S. 722 (2002), can be applied to claims construction. See Accuscan, Inc. v. Xerox Corp., 2003 WL 22148905, at *1 (Fed. Cir. Sept. 17, 2003) ("Since [the restriction of prosecution history estoppel] on the doctrine of equivalents applies "only where claims have been amended for a limited set of reasons," Warner-Jenkinson, 520 U.S. at 32, prosecution history estoppel does not apply to claim construction, literal infringement analysis, or when there is no relevant amendment during prosecution of the patent application. ... Contrary to prosecution history estoppel which limits the doctrine of equivalents, Warner-Jenkinson, 520 U.S. at 30, prosecution disclaimer applies to the determination of literal infringement by excluding from the claim construction any claim scope that has been clearly and unmistakably disavowed during prosecution."). See also Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1367 (Fed. Cir. 2003); Ballard Medical Products v. Allegience Healthcare Corp., 268 F.3d 1352, 1358-59 (Fed. Cir. 2001); Southwall Tech, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995).

 $^{^7}$ These references are cabined to specific claims and do not refer generally to the "invention," "application," or other broader context such that the remarks can be considered to apply to all claims then pending. <u>See</u>

The corresponding structure is a computer programmed to execute the recited function, "produc[ing] at least one subset of sequenced checkpoints defining temperatures and times for a selected cycle of [PCR], " pursuant to a disclosed algorithm, which is illustrated in the '675 Patent in Figures 6 and 7 and PCR Examples I-III at col. 52, 11. 44-54, col. 54, 11. 20-34 and col. 56, 11. 40-53, and discussed beginning at col. 12, 1. 61 and ending at col. 17, 1. 31. Focusing on example II, lines 24-30 correspond to the claim language "at least one subset of sequenced checkpoints;" lines 20-24 correspond to "which can be repeated a user-defined number of times;" and lines 31-34 correspond to "before the checkpoint following the last checkpoint in the subset of sequenced checkpoints is accessed." The corresponding algorithm is thus: a subset of sequenced heating, cooling, and/or temperature maintaining steps in accordance with a PCR protocol where the subset can be cycled a user-defined number of times after which a post-cycling temperature step is accessed.8

The link data field, represented in Figure 7 as step 109 (and Figure 6 as 108) is not corresponding structure. The

Ballard, 268 F.3d at 1360.

⁸ Figures 6 and 7 of the '675 Patent comport with this analysis. For example, steps 81 through 99 of Figure 7 depict "at least one subset of sequenced checkpoints," steps 101 through 105 "which can be repeated a user-defined number of times," and step 111 "before the checkpoint following the last checkpoint in the subset of sequence checkpoints is accessed."

language in the claim does not invoke this step. As noted above, the qualifying phrases - "where said subset is less than the total number of checkpoints which will be accessed in sequence" and "which can be repeated a user-defined number of times before the checkpoint following the last checkpoint in the subset of sequenced checkpoints is accessed" - describe what occurs after a PCR cycle (whether or not such cycle is repeated a user defined number of times), namely, a checkpoint is accessed after the subset of sequenced checkpoints inputted by the user has been accessed, but the claim does not impose the function of accessing the checkpoint following the subset on the user controllable Further, even if the claim did so, the link data field would not constitute corresponding structure as it functions to indicate whether linking is to occur not the further function of step 111, to retrieve the first checkpoint of the new temperature profile. See '675 Patent, col. 15, 11. 49-52; col. 17, 11. 20-26.

While the specification includes a "link data field" as part of "every temperature profile," '675 Patent, col. 15, ll. 41-44; col. 17, ll. 15-17, the functions of "defining" or "producing" or "programming" at least one subset of sequenced checkpoints for a single temperature profile are clearly differentiated from the function of linking two different temperature profiles: the former described as a cycle or temperature profile comprised of

checkpoints (connoting temperature and timing), <u>see e.g.</u>, col. 12, 11. 30-42; col. 13, 11. 3-5; col. 15, 11. 55-60; col. 16, 11. 48 - col. 17, 11. 6, and the latter described as a subsequent linking function should the user desire to perform another cycle of DNA amplification at different temperature checkpoints, <u>see e.g.</u>, col. 15, 11. 37-59. The claims do not refer to the later step of linking to different temperature profiles.

Finally, none of the references in the prosecution history cited by defendants demonstrates that the patentee "expressly relinquished" the scope of claim 17 such that it must be construed to include a link data field as corresponding structure. Omega Eng'q, 334 F.3d at 1323. While the excerpt from the November 9, 1992 amendment, see Defs. Markman App. Vol. 1 [Doc. #642] Ex. 19 at 14-16, comments on the language "defining one subset of sequenced checkpoints ... is accessed," it defines steps 82 to 92 as a "subset of checkpoints" that is "less than the entire sequence of checkpoints," demonstrating that claim 17's "produc[ing] at least one subset of sequenced checkpoints" does not implicate the use of a link data field. The further reference to steps 94 to 106 and 111, see id. at 16 ("... [steps 82 to 92] is a subset of checkpoints that can be repeated a userdefined number of times [steps 94 to 106] before going on to the next checkpoint in the sequence [111]."), emphasizes that steps 82 to 92 can be repeated multiple times as desired by the user

before moving to a new temperature profile and therefore, like the claim language "before the checkpoint following ... is accessed," describes what can occur after a PCR cycle but does not impose such limitation on the user-controllable means of the claim. Similarly, the re-examination prosecution history of claim 17 does not unambiguously distinguish prior art on the basis of a link data field. See Defs. Markman App. Vol. 3 [Doc. #645] Ex. 38 at 1, 18-19.9

5. "user-controllable means programmed to produce at least one subset ... "

Claim 11 (from which claim 17 depends) was amended during

⁹ The prosecution history question is a close one. Because claims 11, 33, 40, and 44 were "cancelled or amended" during the re-examination of the '675 Patent, a plausible reading of the prosecution history could lead to the conclusion that the patentability of claims 17, 33, and 45 "was seen to rest, completely or in large part, on the deficiency of the Techne [TP-16] controller." Defs. Markman App. Vol. 3 [Doc. #645] Ex. 38 at 13, 18-19. The absence of reference to the Techne TP-16 where those claims are explicitly distinguished from European Patent Application '408 (the "'408 Patent"), see id. at 18-19, can be explained by the patentee having already pointed out that the '408 Patent did not suffer the deficiency of the Techne TP-16, $\underline{\text{see}}$ id. at 12, and thus continued teaching away from the Techne TP-16 was "irrelevant," id. at 13 n.1. However, even defendants' reading would not require claims 17, 33, and 45 to be construed to include a link data field. The patentee did not distinguish the Techne TP-16 on the basis of the existence of a link data field or linking function; rather, the patentee explicitly acknowledged that the Techne TP-16 could link multiple temperature profiles. See Applera Markman App. [Doc. #678] Ex. 22 at 1-2, 9-12; see Defs. Markman App. Vol. 1 [Doc. #642] Ex. 16 at 1-2, Ex. 19 at 4-5, 26-27, 32-33, Ex. 20 at 1-5. The patentee distinguished the Techne TP-16 as incapable of allowing "the user \dots to specify that any particular [temperature profile] in the sequence of linked programs be run more than once." Applera Markman App. [Doc. #678] Ex. 22 at 11. The innovation of the '675 Patent is found in the claim language "which can be repeated a user-defined number of times before the checkpoint following the last checkpoint in the subset of sequenced checkpoints is accessed." The prepositional phrase beginning with "before..." describes steps already in Techne TP-16 and focuses the reader on the critical difference, the new invention's capacity to allow a user to run a single temperature profile multiple times prior to any known linking capability.

re-examination from user controllable means for defining a PCR protocol to user controllable means programmed to produce the checkpoints in a PCR protocol. The parties agree that the corresponding structure includes a computer programmed to perform a PCR protocol. See Markman Tr. Vol. I [Doc. #681] at 176-77 ("So, the parties are in agreement with respect to claims 33 and 17 on the issue of whether or not the computer needs to be programed already with a PCR profile. ... [H]ere we agree it should be programmed to perform, not merely programmed to enable the user to select or program in the steps for the subset.").

B. Claim 33

Claim 33 of the '675 Patent reads as follows:

Apparatus capable of cycling a reaction mixture in a polymerase chain reaction mixture in a polymerase chain reaction process that includes multiple cycles of the steps of thermal denaturation of double stranded DNA, primer annealing to single-stranded DNA and primer extension by a DNA polymerase, said apparatus comprising:

- a heat-conducting container for holding a reaction mixture;
- means for heating and cooling said container to or at any of a plurality of temperatures and having a control input for receiving a control signal controlling whether said container is heated or cooled;
- a computer means, coupled to said control input of said means for heating and cooling, comprising means for receiving, storing, and accessing a plurality of checkpoints from a user, each said checkpoint defining a first time for which said container is to be maintained at a first temperature, said accessing a plurality of checkpoints comprising generating control signals therefrom at the control input of said means

for heating and cooling to cause said first temperature to be achieved at said container and maintained for said first time;

wherein said computer means further comprises means for arranging said checkpoints in a sequence in which they are to be automatically accessed, and means programmed to define at least one subset of sequenced checkpoints during which said denaturation, hybridization, and extension occur, where said subset is less than the total number of checkpoints which will be accessed in sequence, which can be repeated a number of times before the checkpoint subsequent to the last checkpoint in the subset of sequence checkpoints is accessed.

The resolution of the construction disputes for claim 17 in Part I.A. controls all but one of the parties' disputes in claim 33, including the construction of claim 33's preamble, and the following claim language: "means for heating and cooling to or at any of a plurality of temperatures," "a computer means ... said accessing a plurality of checkpoints comprising generating control signals therefrom at the control input," and "means programmed to define..."

The remaining dispute focuses on the claim language "which can be repeated a number of times." The corresponding phrase in claim 17 is "which can be repeated a user defined number of times." In contrast to claim 17, the plain language of claim 33 does not specify that the number of times a subset can be repeated is user-defined, and will therefore not be construed to contain that limitation.

C. Claim 45

Claim 45 of the '675 Patent depends from cancelled claim 44, which in turn depends from cancelled claim 40. Accordingly, the Court construes claim 45 as containing all the limitations of claims 40 and 44. Claims 40 and 44, with underlined text showing the language of claim 45, reads as follows:

Apparatus capable of cycling a reaction mixture in a polymerase chain reaction process comprising:

- a heat-conducting container for holding a reaction mixture;
- means for heating and cooling said container to or at any of a plurality of temperatures and having a control input for receiving a control signal controlling whether said container is heated or cooled, wherein said means for heating and cooling said container includes a metal block supporting said container and wherein said metal block further comprise[s] a plurality of receptacles for supporting a plurality of containers;
- a computer means, coupled to said control input of said means for heating and cooling, comprising means for receiving and storing a plurality of data input from a user corresponding to a temperature cycling profile, said cycling profile including heating, cooling and temperature maintaining steps and for accessing said plurality of said stored data and generating control signals therefrom at the control input of said means for heating and cooling to cause said temperature cycling profile to be achieved at said container;
- wherein said computer means further comprises usercontrollable means for configuring said temperature
 cycling profile as a sequence of heating, cooling and
 temperature maintaining steps which are to be
 automatically accessed upon a command from the user,
 and user-controllable means for defining at least one
 subset of sequenced steps, where said subset is less
 than the total number of steps which will be accessed
 in sequence, which can be repeated a user-defined
 number of times before the step following the last step
 in the subset or sequenced steps if accessed.

The resolution of the construction disputes for claim 17 in Part I.A. controls the parties' construction disputes regarding claim 45's preamble and the following claim language: "means for heating and cooling to or at any of a plurality of temperatures," and "a computer means ... generating control signals therefrom at the control input." The two remaining construction disputes and one non-construction issue are resolved as follows:

"wherein said metal block further comprise[s] a plurality of receptacles for supporting a plurality of containers"

This claim element limits the metal block to one having a plurality of recesses. As acknowledged by Applera, the term "receptacles" equates to the written specification's "reaction well" or "reaction vessel." See Markman Tr. Vol. 1 [Doc. #681] at 120:4, 13-15. By further specifying that the "reaction well" of the specification is "for supporting a plurality of containers," the claim designates the first of the two alternative kinds of reaction wells described in the specification, see '675 Patent, col. 7, 1. 63 - col. 8, 1. 3 ("The heat exchanger 10 supports the reaction well 40, which may be a recess machined into the heat exchanger, but preferably is a plastic container which holds the fluids involved in the reaction and which sits in a recess formed in heat exchanger 10..."), because nowhere does the specification envision that the

preferred reaction well, a plastic container which holds fluids, would in turn be used for supporting another container. Thus, the language of the claim as defined in light of the specification rebuts assigning "receptacle" its ordinary meaning.

See e.g., Webster's New World Dictionary of the American Language 1185 (2d college ed. 1984) ("anything used to contain or hold something else; container; vessel.").

"user-controllable means for defining at least one subset of sequenced steps ... which can be repeated a user-defined number of times before the step following the last step in the subset o[f] sequenced steps i[s] accessed."

The claim language requires a computer programmed to permit a user to select a subset of sequenced steps in accordance with a PCR protocol, and not a computer programmed to perform a selected cycle of PCR. The written specification is consistent with this conclusion. See '675 Patent, col. 11, 11. 19-21.

Claim 45's dependence on canceled claims 40 and 44
has no effect on the validity and enforcement of
claim 45.

Claim 45 is valid and enforceable notwithstanding the cancellation of claims 44 and 40. See 35 U.S.C. § 282 ("Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims

shall be presumed valid even though dependent upon an invalid claim."); see also 35 U.S.C. § 112(4); Ortho Pharmaceutical Corp. v. Smith, 959 F.2d 936, 942 (Fed. Cir. 1992); Kloster Speedsteel

AB v. Crucible Inc., 793 F.2d 1565, 1576 (Fed. Cir. 1986); Khyber Tech. Corp. v. Casio, Inc., No. Civ. A. 99-12468-GAO, 2003 WL 21696354, at *1 (D. Mass. Mar. 31, 2003); MPEP § 2260.1 (8th ed. 2001).10

II. The '493 Patent - Claim 16

Claim 16 depends from claim 1. Claim 16 will be construed as containing all the limitations of claim 1. Claim 1, with underlined text showing the language of claim 16, reads as follows:

A thermal cycling system for performing a polymerase chain reaction amplification protocol comprising multiple cycles of the steps of thermal denaturation of double-stranded DNA, primer hybridization to single-stranded DNA, and template-dependent primer extension by a DNA polymerase, comprising:

^{10 &}lt;u>Vectra Fitness, Inc. v. TNWK Corp.</u>, 162 F.3d 1379 (Fed. Cir. 1998) is inapplicable. There the Federal Circuit interpreted the interplay between 35 U.S.C. \S 251 (prohibiting addition of claims that broaden the scope of claims of original patent more than two years after grant of the patent) and 35 U.S.C. § 253 (directing that disclaimer of any complete claim be considered part of the original patent) in holding that the "original patent" for purposes of 35 U.S.C. \S 251 was the patent as issued minus claims subject to a recorded disclaimer under 35 U.S.C. \S 253 such that a reissue application may not enlarge the scope of the non-disclaimed claims more than two years after the grant of the "original patent." Here, claim 45 was part of the $^{\circ}675$ Patent when issued and not part of a reissue application. Accordingly, under 35 U.S.C. \S 282, its validity is unaffected by the cancellation of claims 40 and 44. This conclusion is consistent with a patent's function of providing notice to the public. See Vectra Fitness, 162 F.3d at 1384 ("... the public should be able to rely on the scope of non-disclaimed claims.") (emphasis added)).

- <u>a plurality of reaction mixtures</u> comprising at least one single- or double-stranded nucleic acid sequence to be amplified, four different deoxyribonucleotides, and a pair of oligodeoxyribonucleotide primers for each said at least one nucleic acid sequence to be amplified.
- for said <u>plurality of reaction mixtures</u>, a <u>plurality of</u> heat-conducting reaction chambers.
- in thermal contact with said <u>plurality of reaction chambers</u>, a variable temperature heating and cooling system, <u>which includes a metal block having a plurality of recesses shaped to fit said chambers and a Peltier device</u>, the temperature of said heating and cooling system being computer controllable, and
- a user-initiable computer controllingly coupled to said heating and cooling system, said computer being programmed to vary the temperature of said heating and cooling system and thereby to vary the temperature of said plurality of reaction chambers in accordance with said polymerase chain reaction protocol upon initiation by a user.

The preamble construction dispute here is controlled by the discussion of the preamble of claim 17 above at Part I.A.1.

A. "variable temperature heating and cooling system which includes a metal block ... and a Peltier device"

This claim is not in means-plus-function form. The claim does not contain the word "means," thus giving rise to a "rebuttable presumption that § 112 ¶ 6 does not apply." Apex, Inc. v. Raritan Computer, Inc., 325 F.3d 1364, 1371 (Fed. Cir. 2003) (quotation omitted). Here, viewing "the limitations as a whole" and not relying "on single words of the limitations," id. at 1372, that presumption is not rebutted as the claim recites sufficiently definite structure for performing the function of

heating and cooling that has a reasonably well understood meaning in the art. See id. The term "heating and cooling system" is defined as

An apparatus consisting of an energy source, a method of converting that energy to heat, and a transport system to convey the energy and heat to the point of use....

Electrical energy can be converted directly into heat by means of resistance heaters. Heat pump systems typically use electrical energy to drive the refrigeration compressor and fans; part of the useful heat is waste from the refrigeration process, but most of the heat comes from the air or water source.

McGraw-Hill Encyclopedia of Science and Technology, 408-09 (8th ed. 1997). See also Apex, 325 F.3d at 1373-74 (definitions of "circuit," "interface," and "interface circuit" in technical dictionaries demonstrate that ordinary meaning of claim term "interface circuit" connotes sufficient structure to one of ordinary skill in the art). Further, neither the written specification nor the prosecution history provide any evidence that the patentees intended "heating and cooling system" to have a meaning contrary to this ordinary meaning. See '493 Patent Abstract, col. 5, 11. 10-14, Applera Markman Declaration [Doc. #678] Ex. 2 at 8-9; see also Applera Markman Declaration [Doc. #678] Ex. 3 at 610:11-17. Moreover, the modifier "variable temperature" does not make the structure any less sufficient for purposes of means plus function analysis; rather it further defines the term "heating and cooling system," limiting the scope of those structures covered by it. See Apex, 325 F.3d at 1374;

Personalized Media Communications, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998).

Finally, claim 16 explicitly expounds on the term "variable temperature heating and cooling system" by adding "[which includes] a metal block having a plurality of recesses shaped to fit said chambers and a Peltier device," providing an independent basis for concluding the claim recites sufficient structure to one skilled in the art for performing the heating and cooling function. See Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1303-04 (Fed. Cir. 1999). This is consistent with the written specification, which describes the heat exchanger and Peltier device as sufficient structure to perform the heating and cooling of the reaction chamber. See e.g., col. 7, 1. 66 - col. 8, 1. 12, 51-53.

B. "user initiable computer ... being programmed to vary the temperature of said heating and cooling system and thereby to vary the temperature of said plurality of chambers in accordance with said polymerase chain reaction protocol upon initiation by a user"

This claim is not in means-plus-function form. The presumption against such construction arising from the absence of the word "means" is not rebutted because the claim discloses to one skilled in the art sufficiently definite structure for programming a computer to vary the temperature of a heating and cooling system in accordance with a polymerase chain reaction

protocol, namely, a computer programmed to vary the temperature of a heating and cooling system in accordance with "multiple cycles of the steps of thermal denaturation of double-stranded DNA, primer hybridization to single-stranded DNA, and template-dependent primer extension by a DNA polymerase." '493 Patent, col. 56, 11. 58-62. The prosecution history further contains evidence demonstrating that one skilled in the art would reasonably understand how to program a computer in accordance with a PCR protocol. See Applera Markman Declaration [Doc. #678] Ex. 7 at ¶¶ 6-8, Ex. 8 at ¶ 7.

III. The '610 Patent

A. Claim 1

Claim 1 of the '610 Patent reads as follows:

An apparatus for controlled automated performance of polymerase chain reactions in at least one sample tube containing a known volume of a liquid sample mixture, which apparatus comprises:

- a. A sample block having at least one well for said at least one sample tube,
- b. a computing apparatus,
- c. heating and cooling means controlled by said computing apparatus for changing the temperature of said sample block, and
- d. means for determining the temperature of said block in a first sample interval, wherein said first sample interval is an interval of time designated as time n;

wherein said computing apparatus includes means for determining the temperature of said liquid sample mixture as

a function of the temperature of said sample block over time by utilizing the relationship:

 $Tsamp_n = Tsamp_{n-1} + (TB_n - Tsamp_{n-1}) * tinterval/tau$

where $Tsamp_n$ is equal to the sample temperature in said first sample interval, $Tsamp_{n-1}$ is a sample temperature in a second sample interval immediately preceding the first sample interval, said second sample interval designated as time -1, TBn is equal to the block temperature in said first sample interval, tinterval is a time in seconds between consecutive sample intervals, and tau is a function of thermal characteristics of said apparatus.

1. Preamble: "An apparatus for controlled automated performance of polymerase chain reactions..."

The word "for" is defined as "with the aim or purpose of; suitable to; appropriate for." Webster's New World Dictionary of the American Language 544 (2d ed. 1984). Thus, the preamble describes an intended use for the invention and, as the body of the claim also defines a structurally complete invention for controlled automated PCR such that deletion of the preamble would not affect that structure, it is not limiting. See Catalina

Marketing, 289 F.3d at 808-09. Similarly, even if the preamble were a limitation of the claim, the meaning of the word "for" would require only that the claimed invention be capable of not necessarily limited to the performance of PCR.

2. "a. a sample block having at least one well for said at least one sample tube"

a. "well"

Dictionary definitions of "well" having at least some relation to the claimed invention define the word as "a deep hole or shaft sunk into the earth or "any of various vessels, containers, etc. for holding liquid, as an inkwell," Webster's Deluxe Unabridged Dictionary 2077 (2d ed. 1983), and "A pit dug in the ground....", "A shaft or pit bored or dug in the ground," "A hole or cavity containing or to contain a liquid," and "A sunk receptacle for a liquid, as ink, etc.; also, an indentation or cavity in a dish, tray, etc..., "Oxford English Dictionary Online "well" at 3.a., 7., 11., 11.c. (2003). See also Defs.' Markman Brief [Doc. #642] at 61 n.49. The ordinary meaning of the claim thus requires the block to contain an indentation such as a pit, hole, or shaft sunk into the surface of the sample block, namely, a recess below the surface of the block. This conclusion is consistent with the definition "any of various ... containers ... for holding liquid," which implicates a structure that is complete without any additional structure above the top of the indentation or container.

The ordinary meaning of the claim term "well" is consistent with the written specification, which unambiguously demonstrates that the inventor intended "a sunk receptacle" as the "meaning[] of the term[] in question ... to particularly point out and

distinctly claim the invention." Texas Digital, 308 F.3d at 1203; see also id. ("Because words often have multiple dictionary definitions, ..., the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor."). The summary of the invention refers to the wells in the block as "recess[es]" typically utilizing conical shapes and 17 degree angles relative to the longitudinal axis of the block. See '610 Patent, col. 4, 11. 56-61. The subsequent reference to "[o]ther shapes and angles" in context explicitly directs that the invention can be practiced with wells, i.e. recesses, that are not conical, for example, triangular, or utilized with other than 17 degree angles relative to the longitudinal axis of the block, but not that the fundamental description of the wells as recessed, a description that comports with the ordinary meaning of the word "well," can be altered. 11 In addition, the figures and detailed description of the embodiments of the invention uniformly depict and describe the wells consistent with the recessed description of the summary. See e.g., '610 Patent, Figs. 7, 8, 9, 15, 21A, and 21B; col. 13, 1. 47 - col. 14, 1. 6, and col. 28, 11. 14.

¹¹ Similarly, the reference to the block as "available in a wide variety of materials, shapes and volumes of the sample wells" in '610 Patent col. 3, ll. 41-42 begs the question of what "well" means because the materials, shapes, and volumes for the required wells neither necessitate above surface structures nor are inconsistent with variations in the recesses themselves.

Accordingly, based on the ordinary meaning of the word "well" and the written specification's use of the word in accordance with that meaning, the term "well" is interpreted as recess below the top surface of the block.

b. "... well for said at least one sample tube"

The ordinary meaning of the preposition "for," <u>see</u> Webster's New World Dictionary of the American Language 544 ("with the aim or purpose of; suitable to; appropriate for"), demonstrates the intended use of the well is that it be capable of holding a tube, and does not require that the tube actually be seated in the well, even though "one embodiment" requires the tubes be "seated in the sample block," '610 Patent, col. 8, 1. 65 and col. 9, 11. 31-32, at least while performing PCR.

3. "heating and cooling means controlled by said computing apparatus for changing the temperature of said sample block"

The parties agree that this limitation is subject to 35 U.S.C. § 112. The function is "heating and cooling ... for changing the temperature of said sample block." Ramp and bias cooling are not explicitly recited functions. The doctrine of claim differentiation, see Wenger, 239 F.3d at 1233-34, strengthens this conclusion because the patentee knew how to specifically claim bias and ramp cooling, see '610 Patent, col.

246, 11. 55-63, col. 254, 11. 20-24, col. 255, 11. 13-17, col. 10-15, 19-22, and particularly since claim 26 (col. 246, 11. 55-63) depends from claim 1. See Wenger, 239 F.3d at 1234. However, because "the stringencies of a means-plus function limitation are not to be avoided by the mere addition of a dependent claim that recites the corresponding structure disclosed in the specification," id. at 1233, the Court must continue to step two, to examine the specification of the '610 Patent to determine whether ramp and bias cooling are required as corresponding structures that actually perform and are clearly linked to the explicitly recited function.

In the specification, the structure linked to the recited function of "heating ... for changing the temperature of said sample block" is a film heater, see '610 Patent, Figure 1, col. 11, 11. 52-56, col. 17, 11. 15-17, or a fluid/gas flow heating system, see id. at col. 4, 11. 16-17, 18, 11. 31-35. Whether the film heater is limited to a "multi-zone" heater is a close call. The Court believes that three considerations require the conclusion that the film heater is not so limited: 1.) the claim does not call for multi-zone heating, merely heating; 2.) while not without ambiguity, the specification appears to identify a multi-zone film heater with three separately controllable zones as a preferred embodiment, see '610 Patent, col. 17, 11. 13-17, indicating that claim 1 claims less function than could be

performed by a film heater with multiple zones; and 3.) claim 9, which ultimately depends from claim 1, specifically recites a multi-zone heater as a heating means, see '610 Patent, col. 244, ll. 10-14; see also col. 256, ll. 23-29 (claim 148), giving rise under the doctrine of claim differentiation to a presumption that independent claim 1 should not be construed with such limitation.

The structure in the specification linked to the recited function of "cooling ... for changing the temperature of said sample block" requires a fluid flow cooling system having cooling channels in the block, <u>see id.</u> at col. 6, 11. 8-14, 9, 1. 53 col. 12, 1. 5, and may but is not required to include a bias cooling system, which in turn may be supplied by bias cooling channels, cooling fan and fins formed in the metal of the block, peltier junctions, or constantly circulating tap water, see id. '610 Patent, col. 11, 11. 3-9, 30-32, 60-64. This narrowing of the term "cooling" in the claim is derived from the fact that all disclosures in the specification of structure sufficient to cool the block contain cooling channels or fluid flow paths. this is not a case in which the specification sets forth alternative structures for performing the claimed function and the claim is improperly limited to the specific structure of one such embodiment. See e.g., Micro Chemical, 194 F.3d at 1259. Here, there is no structure disclosed that does not require channels to cool the block. The cooling fan and fins, peltier

junctions, and constantly circulating tap water are disclosed as alternatives to bias cooling channels (structure which the specification explicitly states is unnecessary for some embodiments, see id., col. 11, ll. 3-9, 60-61), but not as alternatives to the required cooling channels or fluid flow paths. When present, the bias cooling system is used with the fluid flow paths or cooling channels to implement one of the patent's improvements over the prior art, namely, control with greater precision of temperature gradients across the block, see <u>e.g.</u>, col. 3, 11. 10-25, col. 4, 11. 16-49, col. 5, 11. 45-52, col. 6, 11. 8-15, col. 11, 11. 30-50. Finally, as "peltier junctions" were well known in the art, see Applera Markman Declaration [Doc. #678] Ex. 3 at 610:11-17, Ex. 28 at 111, 114, 117, such device conveys sufficient alternative structure to bias cooling channels. See Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1381-82 (Fed. Cir. 2001); S3 Inc. v. Nvidia Corp., 259 F.3d 1364, 1370-71 (Fed. Cir. 2001).

In addition, defendants' citations to the prosecution history regarding bias cooling do not demonstrate "the clear disavowal of claim scope," Texas Digital, 308 F.3d at 1204, necessary to read such limitation into claim 1. The cited patentee statements do not discuss any claims currently being asserted by Applera as infringed but were directed to non-asserted claims that explicitly recite bias cooling as a

limitation. <u>See Defs. Markman App. Vol. 3 [Doc. #645] Ex. 29 at 15-20 (in the context of, inter alia, the 1991 Coy Manual, Seiko's European Patent, and the Dean reference, distinguishing claims 132, 133, and 156 by reference to bias cooling, but distinguishing claim 1 by reference to means for determining temperature).</u>

4. "means for determining the temperature of said block in a first sample interval, wherein said first sample interval is an interval of time designated as time n"

The parties agree that this limitation is subject to 35 U.S.C. § 112, ¶6. The function is "determining the temperature of said block in a first sample interval...." The explicitly recited function does not mention reporting or converting the determined temperature. The structure corresponding to the explicitly recited function is a temperature sensor attached to the block, see '610 Patent, col. 18, ll. 60-64, col. 20, ll. 6-10. An analog-to-digital converter is not a corresponding structure because it performs a conversion function, permitting the determined temperature to be read by the CPU, but not the temperature determination function. See id. at col. 47, ll. 48-59.

5. "wherein said computing apparatus includes means for determining the temperature of said liquid sample mixture as a function of the temperature of said sample block over time by utilizing the relationship:

 $Tsamp_n = Tsamp_{n-1} + (TB_n - Tsamp_{n-1}) *tinterval/tau$

... where ... tau is a function of thermal characteristics of said apparatus."

"Tau" is not a constant that has the same numerical value throughout an entire PCR run. The plain language of the claim explicitly defines "tau" as "a function of thermal characteristics of said apparatus," and the term "function" is defined as "a thing that depends on and varies with something else; a quantity whose value depends on that of another quantity or quantities." See Webster's New World Dictionary of the American Language 565 (2d ed. 1984). This conclusion follows the "heavy presumption that [claim terms] mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art," Texas Digital, 308 F.3d at 1202, cannot be overcome by pointing to the method of the preferred embodiment, see '610 Patent, col. 29, 1. 62 - col. 30, 1. 27, and is consistent with extrinsic evidence offered by Applera. See Marguiles Aff. [Doc. #553] at 6.12

The parties agree that the precise algorithm contained in this claim is part of its construction. Accordingly, the Court does not address whether defendants' citations to the prosecution history bar Applera from demonstrating infringement under the doctrine of equivalents because the doctrine of prosecution history estoppel does not apply at the claim construction stage. See supra note 6.

B. Claim 44: "The apparatus of claim 1, further comprising means for overshooting the temperature of said sample block above a desired sample temperature, thereby decreasing an upramp time required for said liquid sample mixture to achieve said desired sample temperature."

Claim 44 of the '610 patent depends from claim 1. Accordingly, the Court construes claim 44 as containing all the limitations of claim 1. The parties agree this limitation is subject to 35 U.S.C. § 112, ¶ 6. The function here is "overshooting the temperature of said sample block above a desired sample temperature." Corresponding structure is found at '610 Patent, Figure 14.1, col. 7, 11. 30-34, col. 66, 11. 24-26, 56-63, which describe a computer programmed with a "controlled overshoot algorithm." The algorithm is illustrated in Figure 14.1 and is said to ensure that the "block temperature often overshoots its final steady state value in order for the sample temperature to arrive at its desired temperature as rapidly as possible," thereby "caus[ing] the block temperature to overshoot in a controlled manner but ... not caus[ing] the sample temperature to overshoot." '610 Patent, Figure 14.1, col. 66, 11. 56-63. While the specification thus appears sufficient to disclose a structure consisting of a computer programmed with the disclosed algorithm, see WMS Gaming v. Int'l Game Tech., 184 F.3d 1339, 1348-49 (Fed. Cir. 1999), Applera does not urge the Court to decide the sufficiency issue at the claims construction stage, see Markman Tr. Vol. III [Doc. #--] at 48:1-11.

C. Claim 158

Claim 158 of the '610 Patent depends from claim 1 (or claim 150). Accordingly, the Court construes claim 158 as containing all the limitations of claim 1. The parties do not appear to be in disagreement regarding the substance of the construction of this claim.

D. Claim 160

Independent claim 160 reads:

In a combination of a thermal cycler for performing a polymerase chain reaction comprising a temperature—controlled metal block having an array of tapered wells in its top surface, and a plurality of individual reaction tubes having similarly tapered lower sections and upper sections which project above the top surface of the block when the tubes are placed in said wells, the improvement comprising means for seating said tubes in said wells, said seating means comprising:

- a) resiliently deformable sealing caps removably attached to said tubes,
- b) a platen,
- c) support means for supporting the platen above the block, and
- d) displacement means associated with the support means for raising the platen above said caps and for lowering it so as to apply a force of at least 30 grams to each cap.

1. Preamble: "In a combination of a thermal cycler for performing a polymerase chain reaction comprising a temperature-controlled metal block having an array of tapered wells in its top surface, and a plurality of individual reaction tubes having similarly tapered lower sections and upper sections which project above the top surface of the block when the tubes are placed in said wells, the improvement comprising" (emphasis designates disputed claim terms)

The parties agree that claim 160 is in "Jepson" format, which "allows a patentee to use the preamble to recite 'elements or steps of the claimed invention which are conventional or known.'" Epcon Gas Systems, Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029 (Fed. Cir. 2002) (quoting Kegel Co. V. AMF Bowling, Inc., 127 F.3d 1420, 1426 (Fed. Cir. 1997) (quoting 37 C.F.R. § 1.75(e)(1996))). "When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope." Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997). "Thus, the form of the claim itself indicates [an] intention to use the preamble to define, in part, the structural elements of [a] claimed invention," id., and thus "the preamble is a limitation in a Jepson-type claim." Epcon, 279 F.3d at 1029.

As discussed above with respect to claim 1 of the '610 Patent, the word "for," defined as "with the aim or purpose of; suitable to; appropriate for," Webster's New World Dictionary of the American Language 544 (2d ed. 1984), indicates that the

preamble here describes an intended use for the invention not a structural limitation. As the remaining structure in the preamble coupled with the body of the claim also defines a structurally complete invention for PCR with improved means for seating tubes, the intended use is not a limitation, even though the preamble is in Jepson format. See Rowe, 112 F.3d at 478. In addition, even if "for performing a polymerase chain reaction..." were considered a structural limitation, the meaning of the word "for" would require only that the claimed invention be capable of but not necessarily limited to performing PCR.

As concluded with respect to claim 1, the ordinary meaning of "well" is a sunk receptacle or recessed hole. The preamble to claim 160 comports with this interpretation for the language "wells in its top surface" is further explained by "tubes ... which project above the top surface of the block when the tubes are placed in said wells." The tubes would not be said to "project", that is, "protrude," Webster's New International Dictionary 1979 (2d ed. 1961), "above the top surface of the block" if they were still surrounded or encompassed by the "wells." Accordingly, and for the reasons discussed above with respect to claim 1, the preamble here does limit the structure to wells recessed below the top surface of the block.¹³

¹³ To the extent defendants' construction calls for tubes to be actually placed in the wells, the use of the word "when" in the preamble contravenes such limitation because such tubes need not be ever present in the wells as part of the invention. <u>See Intel Corp. v. U.S. Int'l Trade Comm'n</u>, 946 F.3d

2. "means for seating said tubes in said wells, said seating means comprising"

Notwithstanding the use of the word "means" and the recital of a function, namely, "for seating said tubes in said wells," this claim is not in means plus function format because it recites sufficient structure to perform entirely the recited function. See Rodime, 174 F.3d at 1302-04. The claim itself states that said seating means comprises "resiliently deformable sealing caps removably attached to said tubes, a platen, support means for supporting the platen above the block, and displacement means " Coupled with the PCR machine disclosed in the preamble, these claim elements provide not only the structure sufficient to seat tubes in the wells but also indicate the relationship of the caps to tubes, location of the platen with respect to the metal block and caps, and structure sufficient to support the platen and lower it down on the tubes. structure is sufficient for performing the function of seating the tubes in the wells. <u>See</u> '610 Patent, Figure 19 and col. 33, 11. 47-64.

a. "resiliently deformable sealing caps removably attached to said tubes"

"Resilient" is defined as "bouncing or springing back into shape, position, etc. after being stretched, bent, or, esp.,

^{821, 832 (}Fed. Cir. 1991).

compressed," Webster's New World Dictionary of the American Language 1210 (2d college ed. 1984), and "deformable" as "[capable of being acted on so as] to change the shape of by pressure or stress," id. at 371. Thus, centering on the language of the claim in the first instance, the ordinary meaning is a sealing cap that can be compressed by pressure or stress and still bounce or spring back into shape after the pressure is removed. Further, nothing in the specification demonstrates that the patentee acted as his or her own lexicographer so as to alter the ordinary meaning of the phrase. To the contrary, the specification's description of the "resiliently deformable sealing caps" is consistent with the phrase's ordinary meaning.

See '610 Patent, col. 6, 11. 55-56, col. 34, 11. 47-63, col. 36, 11. 58-67.

Defendants' proposal to import precise numerical limitations from the preferred embodiments of the claimed invention is inappropriate. Reading numerical precision into imprecise claim terms is usually incorrect. See Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1551-54 (Fed. Cir. 1996) (importing precise numerical range from written specification into claim term "relatively small" only where patentee removed a greater range in successive patent applications and in the process explicitly informed the examiner that the smaller range represented the invention's peak range). Here, defendants'

citations to the prosecution history demonstrate merely that the patentee distinguished prior art on the basis of the existence of resiliently deformable sealing caps in the claimed invention, see Defs. Markman Vol. 3 [Doc. #645] Ex. 29 at 20, not on the basis of the precise deformable characteristics of the preferred embodiments. See Kopykake Enters., Inc. v. Lucks Co., 264 F.3d 1377, 1382 (Fed. Cir. 2001) (distinguishing prior art on the basis that it did not disclose "screen printing" demonstrated no disclaimer of claim scope with respect to any particular construction of the term "screen printing").

b. "platen"

The term "platen" is defined as "a flat plate; esp. one that exerts or receives pressure." Merriam Webster's Collegiate Dictionary 891 (10th ed. 1996). The specification's use of the term "platen" is consistent with its ordinary meaning. See '610 Patent, col. 33, 11. 47-57 and Figure 19. The prosecution history cited by defendants demonstrates that the patentee distinguished prior art both on the basis of the existence of the platen (as opposed to the precise specifications of how the platen works in the preferred embodiment), see Defs. Markman App. Vol. 3 [Doc. #645] Ex. 29 at 19-20, and contact with caps versus direct contact with a cavity, see id. at 20. Accordingly, this direct contact limitation will be added to the ordinary meaning

c. "support means for supporting the platen above the block"

The parties agree that this claim element is in means plus function form. The function here is "supporting the platen above the block." The corresponding structure includes the "sliding cover" (316) and the "lead screw" (312) of '610 Patent, Figure 19, <u>see id.</u> at col. 33, 11. 47-54, but not the sliding rails (320 and 322) of the same depiction, <u>see id.</u> at col. 33, 11. 58-59. The sliding rails do not support the platen above the block rather permit the sliding cover to slide along the rails. sliding rails are thus not necessary to perform the support function recited in the claim but can be characterized as more particularized defining of the details of the preferred sliding structure unrelated to the recited function. See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1308-09 (Fed. Cir. 1998). The prosecution history cited by defendants demonstrates only that the patentee distinguished prior art (the 1991 Coy Manual, European and Johnson patents) on the grounds that they did not have any support means, not that they did not have the sliding structures disclosed in the patent.

 $^{^{14}}$ Although defendants at one time appeared to argue for a construction including the limitation that the platen be heated, <u>see</u> Defendants' <u>Markman</u> Brief [Doc. #642] at 81-82, defendants have since clarified that their construction does not require the platen to be heated. <u>See Markman</u> Tr. Vol. II [Doc. #682] at 393:4-17.

<u>See</u> Defs.' Markman App. Vol. 3 [Doc. #645] Ex. 29 at 17, 20.

d. "displacement means associated with the support means for raising the platen above said caps and for lowering it so as to apply a force of at least 30 grams to each cap"

The parties agree this claim element is in means plus function format and that the corresponding structure includes a lead screw. They disagree only on the construction of the embedded "support means," whether it includes the structure to enable the cover to slide or not. This issue was decided by the Court's construction of support means, which did not require sliding rails as a part thereof.

IV. Conclusion

As set forth above, the Court has construed the disputed terms in claims 17, 33, and 45 of the '675 Patent, claim 16 of the '493 Patent, and claims 1, 44, 158, 160, 161 and 163 of the '610 Patent.

IT IS SO ORDERED.

/s/

Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut, this 19th day of November 2003.